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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,194	08/18/2003	Rajesh Suresh Kshirsagar	116875	1110

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EXAMINER	
QAZI, SABIHA NAIM	
ART UNIT	**PAPER NUMBER**
1612	

MAIL DATE	DELIVERY MODE
03/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/642,194	KSHIRSAGAR ET AL.	
	Examiner	Art Unit	
	Sabiha Qazi	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,9-16,19 and 20* is/are pending in the application.

4a) Of the above claim(s) *19 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 9-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *19 and 20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Non-Final Office Action

Claims 1-6, 9-16 and 19-20 are pending. Claims 19 and 20 are withdrawn as non-elected invention. No claim is allowed. The Applicants have filed a terminal disclaimer on copending application 10/222,930 now abandoned.

Summary of this Office Action dated 3/8/08

1. Continued Examination Under 37 CFR 1.114
2. 35 USC § 112 (2)--Rejection
3. 35 USC 103 (a)--- Rejection
4. Response to Remarks
5. Communication

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/17/2007 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-6, 9-16 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Citation of "other pharmaceutically acceptable excipients" in claim 1 does not have metes and boundaries.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole

would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 and 9-16 are rejected under 35 U.S.C. 103 (a) as being unpatentable over ZHANG et al (US Patent 6083532) and MEHTA (US 6,620,439).

Applicant Claims

1. A sustained release pharmaceutical composition comprising a cephalosporin antibiotic, a mixture of polymers of galactomannans and a neutral swellable polymer, and other pharmaceutically acceptable excipients, wherein the galactomannans are selected from the group consisting of xanthan gum, guar gum and locust bean gum, and the neutral swellable polymer is poly (ethyl acrylate: methyl methacrylate) 2:1.

6. The composition according to claim 1, wherein the cephalosporin antibiotic is selected from Cephalexin, Cefprozil, Cefditoren pivoxil, Cefadroxil, Cefpodoxime proxetil, Cefuroxime axetil, Cefaclor, Cefamandole, Cefoxitin, Cephalothin,

ZHANG reference teaches sustained release pharmaceutical compositions which contain "a xanthan gum".

ZHANG et al teaches the formulation of a tablet for **sustained release** of a drug comprising an effective amount of a drug to be released at a controlled rate and a sustained release formulation, said sustained release formulation comprising at least three different types of polymers including a pH dependent gelling polymer, a pH independent gelling polymer and an enteric polymer, wherein said pH independent gelling polymer, a polyacrylate material such as **Eudragit RTM. L or Eudragit.RTM. S,** comprises a **xanthan gums**. See the entire document especially abstract and all claims particularly claim 2-13, which contains xanthan gum and polyacrylate polymer (claim 8).

Instant invention differs from the ZHANG in claiming a **composition containing** neutral swellable polymer is Eudragit NE 30D, a poly (ethyl acrylate: methyl methacrylate) 2:1 wherein

ZHANG teaches , a polyacrylate material such as Eudragit RTM. L or Eudragit.RTM. S.

MEHTA teaches oral pharmaceutical formulations of a dose of therapeutic agent for once daily administration prior to sleep having excellent time specific controlled release properties. A substantial percentage of the controlled release dose reaches the blood stream during the dosing period of 5 to 24 hours following oral administration. The method for preparing the formulations provides pharmaceutical preparations for oral administration in both tablet and capsule dosage form. See the abstract. The outer rate controlling layer contains a water insoluble polymer, which may be ethyl cellulose, a copolymer of acrylic and methylacrylic acid esters, which is physiologically acceptable, water insoluble, and permeable to the release of drug contained in the drug layer. Suitable water insoluble polymers include for example, **Eudragit RL 30 D, Eudragit RS 30D, or a poly(meth)acrylate polymer, such as Eudragit NE 30 D, and Eudragit NE 40 D, or a combination thereof. Most preferably, the poly(meth)acrylate polymer, Eudragit NE 30 D, is used in formulating the controlled release coating. Eudragit NE 30 D, Eudragit RS 30 D and Eudragit RL 30 D** polymers are available from Rhom Pharma, D-6108 Weiterstadt 1, Dr. Otto-Rohm-Str. 2-4, Germany. Eudragit NE 30 D and Eudragit NE 40 D are pH independent polymers available as a 30% or 40% aqueous dispersion. **Eudragit RS 30 D and Eudragit RL 30 D are available as aqueous dispersions containing 30% dry substances. See lines 17-39, column 7.** In a preferred embodiment of the invention the binder agent in the drug layer and the innermost drug sealing layer is hydroxypropylmethyl

cellulose and the outer rate controlling layer is **Eudragit NE 30 D**. See lines 36-39 in column 7. See also examples.

It would have been obvious to one skilled in the art at the time of invention to prepare a sustained release formulation of cephalosporin antibiotic, because the prior art teaches a pharmaceutical composition for controlled release and sustained release of an active ingredient, said composition comprising cefaclor, cephalexin, controlled rate and a sustained release formulation because all the critical elements of the instant invention are taught by the references. MEHTA teaches use of neutral swellable polymer is poly (ethyl acrylate: methyl methacrylate) 2:1 in formulating sustained release drugs.

The amounts and proportions of each ingredient are result of effective parameters chosen to obtain the desired effects. It would have been obvious to vary the ratios of active ingredients to optimize the desired effect when the invention has been taught by the prior art of record.

No criticality of present invention was noted and no unexpected results or novelty was found.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Response to Remarks

- 35 USC § 112 - First Paragraph_Written description rejection is withdrawn because claims are amended.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day except Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sabiha Qazi/

Primary Examiner, Art Unit 1612